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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/789,433 | 02/27/2004 | Mark Thomas Muldoon | 19596-0571 (45738-296417) | 5696 |

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| EXAMINER | |
|---|---|
| HINES, JANA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/789,433 | MULDOON ET AL. | |
| | Examiner | Art Unit | |
| | Ja-Na Hines | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 August 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 are drawn to a ligand specific for mammalian troponin, wherein the ligand comprises a molecule that binds to a mammalian molecule, but not an avian troponin molecule, wherein the ligand is an antibody produced by immunizing an animal with a peptide having ONE of the amino acid sequences selected from the group consisting of SEQ ID NO: 2-6, 9-13 and15-35, classified in class 424, subclass 156.1.

II. Claim 9 is drawn to an antigen for the production of an antibody specific for mammalian troponin molecule, wherein the antigen comprises an isolated peptide having ONE of the amino acid sequences selected from the group consisting of SEQ ID NO: 2-6, 9-13 and15-35, classified in class 424, subclass 184.1.

III. Claims 10-18 are drawn to an assay for detecting a mammalian troponin molecule in a sample, the assay comprising: a reaction step and a detecting step, wherein the ligand is an antibody is an antibody produced by immunizing an animal with a peptide having ONE of the amino acid sequences selected from the group consisting of SEQ ID NO: 2-6, 9-13 and 15-35, classified in class 435, subclass 7.1.

IV. Claim 19 is drawn to a method of making an antibody that is specific for a mammalian troponin molecule and not specific for an avian troponin

molecule, comprising administering to an animal an immunogenic amount of a peptide having ONE of the amino acid sequences selected from the group consisting of SEQ ID NO:2-6, 9-13 and15-35, classified in class 436, subclass 547.

2. The inventions are distinct, each from the other because of the following reasons:

(a) Inventions I and II are patentably different products. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions. Group I is drawn to a ligand, while Group II is drawn to an antigen having a specifically recited amino acid sequence. The groups are directed to products that are distinct physically, structurally and functionally, and are therefore patentably distinct, each group from the other. For instance, the ligand of Group I comprises a molecule that binds to a mammalian troponin molecule, which is unlike the antigen of Group II, since the antigen produces an antibody specific for a mammalian troponin molecule. Furthermore, the product of group I can be produced by immunizing an animal a peptide having the same biochemical structure as recited by the product of Group II or produced naturally. Thereby, making the antigen of Group II distinct from the ligand of Group I. Therefore, one is not required to practice the other. Each group comprises separate and distinct products.

Furthermore, searching the inventions of Groups I and II would impose a serious search burden. The inventions have a separate status in the art as shown by their distinct structure. Thus the different products require different searches. An amino acid sequence search of the antigen is not necessary for a determination of novelty and unobviousness of the ligand. Moreover, a search of Group I is not required to identify the antigen of Group II. Furthermore, the ligand of Group I may be known even if the antigen of Group II is novel. In addition, the technical literature search for the ligand of Group I and the antigen of Group II are not coextensive, e.g., the ligand of Group I may be characterized in the technical literature prior to discovery of or sequence of Group II.

(b) Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the assay for detection reacts the sample with a ligand that is specific for the mammalian troponin molecule. The specification teaches that ligand refers to molecules such as antibodies, proteins, peptides, polypeptides,
amino acids, polynucleotides, carbohydrates, sugars, lipids, organic molecules, and polymers. Thus the instant assay of Group III can be practiced with a materially different product, than the product of Group I. Therefore, the inventions have been shown to be distinct.

Furthermore, searching the inventions of groups I and III together would impose a serious search burden. In the instant case, the search of the proteins and the detection assay are not coextensive. The inventions of Groups I and III have a separate status in the art as shown by their different classifications. Thus the ligand of Group I requires a different search than the assay for detection. Searching the reaction step and detection step comprising detecting complex formation to measure the presence or amount of troponin in the sample as recited in Group III is not necessary for a determination of novelty and unobviousness of the ligand. Moreover, a search of Group I is not required to identify the assay of Group III. Furthermore, the ligand of Group I may be known even if the detection assay of Group III is novel. In addition, the technical literature search for the ligand of Group I and the detection assay of Group III are not coextensive, e.g., the ligand of Group I may be characterized in the technical literature prior to discovery of the detection assay of Group III.

(c) Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of Group IV is drawn to a making antibodies, which is a materially different product when compared to the product of Group I. Group I is drawn to ligands, however ligands encompass more than just antibodies. Ligands refer to proteins, peptides, polypeptides, amino acids,

polynucleotides, carbohydrates, sugars, lipids, organic molecules, and polymers; however the method of Group IV does not teach making those products. Furthermore, all of the named ligand can be made naturally or without administration to an animal. Therefore, the inventions have been shown to be distinct.

Accordingly, searching the inventions of Groups I and IV together would impose a serious search burden. In the instant case, the search of the ligand and the method of making antibodies are not coextensive. The inventions of Groups I and IV have a separate status in the art as shown by their different classifications. A ligand search is not necessary for a determination of novelty and unobviousness of the method for making antibodies. Moreover, a search of Group I is not required to identify the method of making antibodies as recited by Group IV. Furthermore, the ligand of Group I may be known even if the method of Group IV is novel. In addition, the technical literature search for ligands of Group I and the method of making antibodies of Group IV are not coextensive, e.g., the ligand of Group I may be characterized in the technical literature separately from the method of Group IV.

(d) Invention IV and either of II, or III are unrelated because neither the product nor the method from Groups II and III are used or otherwise involved in the method of Group IV.

(e) With respect to Groups I-IV, the groups are drawn to peptides having ONE of the amino acid sequences selected from the group consisting of SEQ ID NO: 2-6, 9-13

and 15-35. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: these products appear to constitute patentably distinct inventions for the following reasons: the numbered groups are directed to amino acid sequences molecules comprising SEQ ID NO: 2-6, 9-13 and 15-35, which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct amino acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention. Thus applicant must select ONE specific sequence for the associated Group election.

3. The inventions of Groups I-IV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-IV together.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
August 14, 2006